Massachusetts Department of Public Health
Division of Epidemiology and Immunization

MODEL STANDING ORDERS

Immune Globulin (Human) USP

These model standing orders are current as of February 2001. All standing orders should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Intramuscular (IM) Immune Globulin (IG) is indicated for passive immunization to protect against:
1. hepatitis A virus (HAV); and
2. measles

(These orders do **not** include the use of IG for replacement therapy or other therapies.)

1. Hepatitis A

a. Preexposure:

1) Travel: While hepatitis A vaccine is preferred for those who need long-term protection, IG is **recommended** for preexposure prophylaxis for travelers to areas of high or intermediate endemnicity* who are:

- ≤ 2 years of age;
- traveling < 4 weeks after receiving the first dose of hepatitis A vaccine; or
- allergic to a component of hepatitis A vaccine.

* Countries include those other than the United States, Australia, Canada, Japan, New Zealand and Western Europe.

2) Day Care Settings: IG is **recommended** for unimmunized individuals entering a day care setting with case(s) of hepatitis A, if it is ≤ 6 weeks after the onset of the last case.

b. Postexposure:

IG is **recommended** for previously unvaccinated persons in the following situations, if it is ≤ 14 days after exposure:

1) Household and sexual contacts of persons who have serologically confirmed HAV.

2) All staff and attendees of day care centers or homes if:

- ≥ 1 case of HAV are recognized in children or staff; or
- cases are recognized in ≥ 2 households of center attendees.

(In centers that do not provide care for children in diapers, IG need only be given to classroom contacts of the index case. When an outbreak occurs [i.e., HAV in ≥ 3 families], IG should be considered for members of households that have children [center attendees] in diapers.)

3) All foodhandlers at a location where a foodhandler has been diagnosed with HAV.

- IG administration to patrons is usually not recommended, but may be considered if:
  - during the time when the foodhandler was infectious, the foodhandler both directly handled uncooked foods or foods after cooking and had diarrhea or poor hygienic practices; and
  - patrons can be identified and treated ≤ 14 days after exposure.

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4) IG should be **considered** for close contacts of cases in schools, hospitals or other work settings. IG is **recommended** for close contacts of an index patient if an epidemiological investigation indicates HAV transmission among students in a school or among patients or between patients and staff in a hospital.

2. Measles

Postexposure: IG will prevent or modify infection if given ≤ 6 days of exposure. IG is **recommended** for exposed susceptibles with contraindications to MMR vaccine, particularly those at increased risk for complications of measles infection such as:

- susceptible pregnant women;
- immunocompromised individuals (non-HIV-infected) who are not severely immunosuppressed;
- **susceptible** asymptomatic HIV-infected individuals (with CD4+ cell counts > 200) if exposed 3 – 6 days prior (if exposed ≤ 3 days prior, they should receive MMR);
- infants < 12 months of age;
- individuals with anaphylactic reactions to neomycin or gelatin; and
- individuals with other contraindications for measles-containing vaccine.

ORDER:

1. Provide patient, parent or legal representative with a copy of the Vaccine Information Statement (VIS) and answer any questions.
2. Screen for contraindications according to Table 1.
3. Give IG intramuscularly (IM) according to the recommended schedule (see Tables 2 - 3). **Always check the package insert prior to administration of any vaccine.**
   a. For children and adults, administer vaccine in the deltoid with a 1- to 2-inch needle, depending on the recipient's weight.
   b. For infants, administer vaccine in the anterolateral thigh with a 7/8- to 1-inch needle. (For certain very young, small infants, a 5/8-inch needle may be adequate.)
   c. A 22- to 25-gauge needle is appropriate for most IM vaccines.

Please note:

- IG should be administered at room temperature.
- No more than 5 mL should be administered in one site in an adult or large child; 1 – 3 mL should be given in one site to small children and infants.
- If a gluteal muscle is used, only the upper outer quadrant should be used, and the needle should be directed anteriorly to avoid injury to the sciatic nerve.

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4. Administration of IG and other vaccines:

   a. Inactivated Vaccines
   IG **can** be administered simultaneously with, or at **any** interval before or after, any inactivated vaccine, including hepatitis A vaccine (see Table 3).

   b. Live Vaccines
   - **Simultaneous administration with IG:** If possible, IG should **not** be administered simultaneously with MMR or varicella vaccine.

     If simultaneous administration of IG with MMR or varicella vaccine, or administration of IG $\leq$ 2 weeks after MMR or varicella vaccines, becomes necessary because of imminent exposure to disease, vaccine-induced immunity may be compromised. These vaccines should be administered at a site remote from the site where IG is administered. The person should be revaccinated or tested for seroconversion $\geq$ 3 months later.

   - **If IG is given first:** The interval between IG and MMR and/or varicella vaccine depends on the dose and indication for IG (see Table 2.)

   - **If MMR and/or varicella vaccine is given first**: Defer IG for $\geq$ 2 weeks (see Table 3.)

     Please note: IG **can** be administered at **any** interval with before or after oral polio vaccine, oral typhoid or yellow fever vaccines.

5. If possible, observe patient for an allergic reaction for 15 – 20 minutes after administering vaccine.

6. Facilities and personnel should be available for treating immediate hypersensitivity reactions.

7. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967.

8. Please see the MIP document, *General Protocols for Standing Orders*, for further recommendations and requirements regarding vaccine administration, documentation, and consent.

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Table 1. Contraindications to IG

Valid Contraindications for Immune Globulin	Invalid Contraindications (Immune Globulin should be given)
Anaphylactic reaction to a previous dose of IG	Mild illness with or without low-grade fever
History of reactions related to anti-IgA antibodies, or history of IgA deficiency. (In such cases, use of IgA-depleted IGIV may reduce likelihood of further reaction).	Recent exposure to infectious disease
	Current antimicrobial therapy
Persons with severe thrombocytopenia or any coagulation disorder that would preclude IM injection. In such cases, IGIV is preferred.	Pregnancy[1]
	Breast feeding

[1] **Pregnancy:** Animal reproduction studies have not been conducted with IG. It is also not known whether IG can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. IG should be given to a pregnant woman only if clearly needed.

Table 2. Hepatitis A and Measles Prophylaxis
Dose and Interval Between Administration of IG and Measles-Containing (MCV) and Varicella Vaccines

Indication	Dose of IG[1]	Time Interval Between IG and Vaccination with MCV or VaricellaVaccine
Hepatitis A		
Preexposure		
1 - 2 months duration of protection	0.02 mL/kg[2]	3 months
3 - 5 months duration of protection[2]	0.06 mL/kg[3,4]	3 months
Postexposure	0.02 mL/kg[5]	3 months
Measles		
Non-immunocompromised contact	0.25 mL/kg[6]	5 months
Immunocompromised contact	0.50 mL/kg[6]	6 months

[1] No more than 5 mL should be administered in one site in an adult or large child; 1 – 3 mL should be given in one site to small children and infants.
[2] Maximum dose = 2 mL
[3] Maximum dose = 5 mL
[4] Repeat every 5 months if continued exposure to HAV occurs.
[5] No maximum dose
[6] Maximum dose = 15 mL

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Table 3. Guidelines for Spacing of Non-Simultaneous Administration of Immune Globulin and Vaccines

First	Second	Recommended Minimum Interval
Immune Globulin	Killed Antigen	None
Killed Antigen	Immune Globulin	None
Immune Globulin	Live Antigen[1]: Measles Mumps Rubella Varicella	 Dose-Related (See Table 2) 3 months 3 months Dose-Related (See Table 2)
Live Antigen[1]: MMR Varicella	Immune Globulin	 2 weeks 2 weeks

[1] IG can be given at any interval before, with or after oral polio, oral typhoid or yellow fever vaccines.

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References:

American Academy of Pediatrics. Active and Passive Immunization. Immunization of Children in Special Circumstances. Hepatitis A. Measles. Varicella. Standards for Pediatric Immunization Practices (Appendix II). In: Pickering LK ed. 2000 Red Book: Report of the Committee on Infectious Diseases, 25th ed. Elk Grove Village, IL: American Academy of Pediatrics: 2000: 6-53,54-79,279-289,388-389,390,394, 624-638,748-758,637.

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CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(No.RR-112):26-30.

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CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1994;43(No. RR-1):1-38.

CDC. Use of vaccines and immune globulins in persons with altered immunocompetence: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1993;42(No. RR-4):1-18.

Immune Globulin (Human) USP package insert, Massachusetts Public Health Biologic Laboratories, Department of Public Health, The Commonwealth of Massachusetts.

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